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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,765	01/14/2004	Per Egnelov	030481-0212	1510
22428	7590	06/30/2006	EXAMINER	
FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			MALLARI, PATRICIA C	
			ART UNIT	PAPER NUMBER
			3735	

DATE MAILED: 06/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/756,765	EGNELOV ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Patricia C. Mallari	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 07 April 2006.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,3-11,14-16 and 20-23 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) 9,11,14 and 15 is/are allowed.  
 6) Claim(s) 1,3-8,10,14 and 20-23 is/are rejected.  
 7) Claim(s) 16 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 14 January 2004 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                     | Paper No(s)/Mail Date. _____ .  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____ .                                  |

## **DETAILED ACTION**

This is a non-final Office action. The allowability of claims 21 and 21 has been withdrawn regretfully in view of newly applied reference US Patent No. 5,246,426 to Lewis et al. Rejections based on the new reference follow.

### ***Claim Objections***

Claims 1, 3-8, 10, 14, 16, and 20-23 are objected to because of the following informalities:

On line 1 of each of claims 1, 3-8, 10, 14, 16, and 21-23 “device” should be replaced with “system”.

On line 3 of claim 20, “device” should be replaced with “system”.

Appropriate correction is required

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-8, 10, 14, and 21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,246,426 to Lewis et al. Lewis teaches an indicator device comprising a body 22, 74, 92 comprising a passage 42 passing through the body 22, 74, 92, the body 22, 74, 92 further comprising a duct 82, 106, 108 extending in the body and having a hemostatically sealed blood accommodating chamber 38, 40 (figs. 1-

6D, 7, and 8B; col. 4, lines 27-48; col. 5, lines 8-42; col. 7, lines 14-49; col. 9, line 15-34 of Lewis). An insertion tube 14, 70 comprises a distal end portion 14b, 70b adapted to be positioned inside the blood vessel and comprising a fluid communication pathway between an liquid inlet opening 70d near a distal end of the insertion tube and the duct. The insertion tube further comprises an opening at the extreme end of the distal end portion (Figs. 1, 6C, 7, and 8B; col. 4, lines 33-39; col. 5, line 65-col. 6, line 2; col. 6, line 56-col. 7, line 13; col. 7, lines 27-34; col. 9, line 16-34 of Lewis). A window 24, 26, 92, 106 comprises an at least semi-transparent section configured to enable visual observation of blood entering into the duct via the inlet opening when the inlet opening is located inside the blood vessel (figs. 4, 5, 6B & C, 7; col. 5, lines 14-23; col. 8, lines 17-27; col. 10, lines 25-30 of Lewis). An elongated member 16 is further included (figs. 1, 6A, 8B of Lewis). The passage and fluid communication pathway are adapted to permit the elongated member to be threaded in a substantially straight path there through between a distal end and a proximal end of the device (fig. 1 of Lewis).

As to the limitation "for visually indicating a pressure of blood inside a blood vessel", the applicants should note that this is merely "intended use" language which cannot be relied upon to define over the prior art since Lewis teaches all of the claimed structural limitations and their recited relationships. The system of Lewis is certainly capable of being used to visually indicate a pressure of blood inside a blood vessel.

Regarding claim 3, the duct opens into the chamber via an aperture 84, 86 having a spill-over edge 78, the aperture being located at a level above a bottom

surface of the blood accommodating chamber 38, 40, whereby return of flow of blood back into the duct is prevented (figs. 4, 6B & C of Lewis).

Regarding claim 4, the blood accommodating chamber 38, 40 is located in the body 22, 74, 92, and the body further comprises the insertion tube 14, 70 extending distally of the body (figs. 1 & 4 of Lewis).

Regarding claim 5, the inlet 70d is located on a side of the insertion tube (fig. 6C & 8B of Lewis).

Regarding claims 6 and 7, the duct extends vertically or horizontally to an aperture 84, 86 opening into the blood accommodating chamber 38, 40 (figs. 4, 6B & C of Lewis), wherein the direction of the duct's extension (vertically or horizontally) is merely "intended use" language since it depends on how the device is held. The device of Lewis may be held such that the duct extends vertically or horizontally. In a horizontal position, a portion of the duct 82 extends above a portion 40 of the blood-accommodating chamber to an aperture 86 into the chamber (figs. 4, 6B & C of Lewis).

Regarding claim 8, the duct 82, 106, 108 exhibits a varying cross-section over its length (figs. 7, 8A, 8B of Lewis).

Regarding claims 10 and 14, the elongated member 16 may be threaded in a substantially straight path through the passage and fluid communication pathway such that the elongated member projects distally past the extreme end of the distal end portion (figs. 1 & 8B; col. 5, line 61-col. 6, line 2 of Lewis).

Regarding claims 21-23, the elongated member 16 wherein the elongated member 16 is considered to be a guide wire, guide rod, or dilator (col. 4, line 32 of

Lewis; also see col. 10, lines 17-38 and figures 3 and 8 of US Patent No. 6,689,070 to Hung which shows a dilator 40 being an elongated member used to advance a catheter into a body opening and similar to the guide wire of Lewis).

***Response to Arguments***

Applicant's arguments with respect to claims 1, 3-8, 10, 14, and 23 have been considered but are moot in view of the new ground(s) of rejection.

***Allowable Subject Matter***

Claims 9, 11, 15, and 20 are allowed. The allowability of claims 9 and 15 were addressed in a previous Office action filed 4/20/05.

Claim 16 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

Regarding claim 11, the prior art of record fails to teach an indicator system for visually indicating a pressure of blood inside a blood vessel, wherein the duct first becomes progressively narrower and then becomes progressively wider, in combination with all of the other limitations of the claim.

Regarding claim 16, the prior art of record fails to teach or fairly suggest an indicator system for visually indicating a pressure of blood inside a blood vessel wherein

the blood accommodating chamber and the duct are dimensioned such that a counter-pressure therein when blood enters will cause a blood meniscus at a lowest possible systolic pressure to be located within the window, in combination with all of the other limitations of the claims.

Regarding claim 20, the prior art of record fails to teach a method for visually indicating a pressure of blood inside a blood vessel, wherein an indicator system comprising a body, insertion, tube, window, and elongated member, as claimed, is provided, and pressure is indicated, in combination with all of the other limitations of the claims. US Patent No. 5,246,426 to Lewis teaches the indicator system as claimed and positioning the distal end portion of the tube inside the blood vessel. However, Lewis lacks indicating the pressure inside of the blood vessel.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Patricia Mallari  
Patent Examiner  
Art Unit 3735

  
ROBERT L. NASSER  
PRIMARY EXAMINER